

## REMARKS

Claims 1 - 6 and 8 are pending in the present application. The following rejections are at issue and are set forth by number in the order in which they are addressed:

1. Claim 8 is rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite;
2. Claims 1, 2, 5, 6, and 8 are rejected under 35 U.S.C. §112, first paragraph as non-enabled.

### 1. The Claims are Definite

Claims 8 stands rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. The Examiner states that the phrase "derived from" is indefinite and that the specification fails to provide a definition for the term "derived from". The definiteness of claim language must be analyzed, not in a vacuum, but in light of 1) the content of the particular specification, 2) the teachings of the prior art, and 3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *See, e.g., In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); *Rosemount, Inc., v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983).

Applicants respectfully submit that the plain meaning of the phrase "derived from" a patient is clear to one of ordinary skill in the art. The standard dictionary definition of "derive" (per Webster's Online Dictionary) is:

**1 a :** to take, receive, or obtain especially from a specified source **b :** to obtain (a chemical substance) actually or theoretically from a parent substance.

The same dictionary defines "from" as follows:

**3 --** used as a function word to indicate the source, cause, agent, or basis.

Thus, the meaning of the phrase "derived from" is to obtain from a specified source. In the claims, the "specified source" is from a "patient."

The Federal Circuit has held that dictionary definitions can properly be utilized to determine the plain and ordinary meaning of a claim term:

It has been long recognized in our precedent and in the precedent of our predecessor court, the Court of Customs and Patent Appeals, that dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms. See Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1380 (Fed. Cir. 2002) ( The ordinary meaning of a claim term may be determined by reviewing a variety of sources, including . . . dictionaries and treatises . . . (internal citations omitted)); CCS Fitness, 288 F.3d at 1366, 62 USPQ2d at 1662 ( [O]ur precedents show that dictionary definitions may establish a claim term's ordinary meaning. ); Optical Disk Corp. v. Del Mar Avionics, 208 F.3d 1324, 1334-35, 54 USPQ2d 1289, 1295 (Fed. Cir. 2000) ( For such ordinary meaning, we turn to the dictionary definition of the term. ); Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1581, 36 USPQ2d 1162, 1166 (Fed. Cir. 1995) ( [W]e see no error in the district court's use of dictionary definitions to ascertain the ordinary meaning of the relevant claim limitation. ); In re Ripper, 171 F.2d 297, 299, 80 USPQ 96, 98 (C.C.P.A. 1948) ( [I]t is clear that in ascertaining the meaning of [the claim term] as it appears herein, reference properly may be made to the ordinary dictionaries. ).

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As resources and references to inform and aid courts and judges in the understanding of technology and terminology, it is entirely proper for both trial and appellate judges to consult these materials at any stage of a litigation, regardless of whether they have been offered by a party in evidence or not. Thus, categorizing them as extrinsic evidence or even a special form of extrinsic evidence is misplaced and does not inform the analysis.<sup>1</sup>

Accordingly, the plain and ordinary meaning of the term "derived from" is to obtain from a specified source. Applicants further note that the Examiner has provided absolutely no reasoning as to why the phrase "derived from" renders the Claim 8 indefinite. Thus, the Examiner has not established a prima facie case of indefiniteness by explaining why the claims are indefinite to a person of ordinary skill in the art. In any event, even if a prima facie case of indefiniteness had been established, it has been rebutted. Accordingly, Applicants respectfully request that the

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<sup>1</sup> *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 2002 U.S. App. LEXIS 21567, \*11 - \*15 (Fed. Cir. 2002).

indefiniteness rejection be removed.

## **2. The Claims are Enabled**

Claims 1 - 6 and 8 are rejected under 35 U.S.C. §112, first paragraph as non-enabled. In particular, the Examiner states that "the specification fails to provide sufficient disclosure for a pre-graft human skin equivalent having a SEC of from about 40 to about 240 pf over a 10 second interval. Thus, claims 1-6 and 8 are rejected under 35 U.S.C. 112 because the amended claims contain new matter."

Applicants first respectfully note that is unclear whether the Examiner is rejecting the claims as not being supported by an adequate written description (i.e., as involving "new matter") or that the specification does not enable one of ordinary skill in the art to make and use the invention. These are two separate requirements, which both derive from the first paragraph of Section 112. Nevertheless, in the interest of obtaining an allowance as quickly as possible, Applicants will address both of these separate requirements.

### **a. The Claims do not include new matter**

The Examiner alleges that the claim limitation of "a pre-graft human skin equivalent having a SEC of from about 40 to about 240 pf over a 10 second interval" is new matter. Applicants respectfully disagree. The Examiner admits that lines 1-20 on page 44 discloses "how to measure the difference of SEC of from about 40 to about 240 pf over a 10 second interval." The claims as originally filed specified an SEC of from about 40 to about 240 pf. The addition of the element of "over a 10 second interval," which has clear support in the specification as admitted by the Examiner, merely serves to clarify how the measurement is being conducted. This limitation has clear support in the specification and thus does not constitute new matter. Moreover, the specification makes it clear that the SEC is being measured on pre-graft skin substitutes. See, e.g., p.44 lines 12-15 which teaches that SEC is measured on *in vitro*, or pre-graft cultures). Thus, the claims limitation "pre-graft" does not add new matter. The term merely serves to define when the SEC measurement is being taken. As such, this ground of rejection should be removed as the claims do not contain new matter.

### **b. The Claims are enabled**

Applicants respectfully submit that the specification enables one of skill in the art to make and use a "a pre-graft human skin equivalent having a SEC of from about 40 to about 240 pf over a 10 second interval." The Examiner has failed to establish a *prima facie* case of nonenablement, and, even if a *prima facie* case had been established, it stands rebutted by the Declaration of Dr. Allen Comer.

**i. No *prima facie* case on nonenablement has been established**

Applicant contends that the Examiner has not established a *prima facie* case of nonenablement. In making a nonenablement rejection, the burden is on the Examiner to make a *prima facie* case of nonenablement that is well grounded in scientific reasoning or evidence. *See In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993); *See also* MPEP §706.03 and §2164.04. This is because without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling (*Wright*, 27 USPQ2d at 1513). The Examiner's nonenablement argument is not grounded in scientific reasoning or evidence. Indeed, the Examiner's argument is completely conclusory because the Examiner provides nothing but the assertion that the claims are not enabled. The Examiner provides no evidence or reasoning as to why the methods and compositions taught in the application do not produce a pregraft human skin equivalent having a SEC of from about 40 to about 240 pf over a 10 second interval. Indeed, the Examiner's statement is devoid of any reasoning or evidence. Accordingly, a *prima facie* case of evidence has not been established.

**ii. The Comer Declaration establishes that the claims are enabled**

Even if the Examiner had established a *prima facie* case of nonenablement (and applicants reassert that he has not), the Declaration of Dr. Allen Comer presents unrebutted evidence that the specification does enable claims to human skin equivalent having a SEC of from about 40 to about 240 pf over a 10 second interval. The instant Office Action contains no reference to this declaration and has made no attempt to rebut the factual evidence offered therein.

In paragraph 5, Dr. Comer states that "these results demonstrate that the methods described in the application allow the production of skin tissue with SEC values within the ranges in the claims." This is factual evidence that establishes that skin equivalents prepared substantially as described in the application exhibit SEC readings (the difference in capacitance

at 10 second intervals) in the claimed ranges prior to grafting. Thus, the Examiner's position has been rebutted by factual evidence of enablement for the claimed ranges. The Examiner has made no attempt to rebut this Declaration, thus the evidence therein is controlling.

Applicants respectfully remind the Examiner that he is required to consider the evidence offered in the Declaration. Instead of responding to the factual evidence presented in the Declaration, the Examiner has essentially repeated verbatim the rejections from the previous Office Action. This approach is not looked upon with favor by the Federal Circuit and does not conform with proper patent practice according the Manual of Patent Examining Procedure (MPEP). The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

**Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . Office personnel should avoid giving evidence no weight, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).**

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A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.<sup>2</sup>

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . . An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.<sup>3</sup>

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<sup>2</sup> MPEP §§2144.08; emphasis added).

<sup>3</sup> *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

Furthermore:

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.<sup>4</sup>

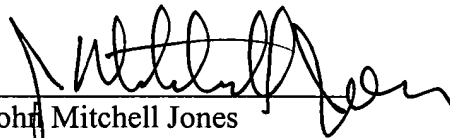
Accordingly, even if the Examiner had established a *prima facie* of nonenablement in the preceding Office Action (and Applicants contend that he did not), the Examiner must respond to Applicants arguments and reweigh the entire merits of the application. **The Examiner has not done so.**

It is particularly problematic that the Examiner, while finalizing the present office action, failed to address all of the Applicants arguments. Accordingly, Applicants request that the nonenablement rejection be removed and the claims passed to allowance.

### CONCLUSION

All grounds of rejection and objection of the Office Action of March 10, 2004 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: 6/7/04

  
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<sup>4</sup> *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).